Supreme Court, U.S.
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No. 97-1380

In The

Supreme Court of the United States

October Term, 1997

ELI LILLY AND COMPANY,

Cross-Petitioner,

v.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Cross-Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

CROSS-RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Does a party against whom no judgment has been entered have standing to seek review of an issue that has no present adverse effect upon it?

PARTIES

The parties are Cross-Petitioner Eli Lilly & Co. and Cross-Respondent Regents of the University of California.[1]

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[1] Pursuant to Rule 29.6, cross-respondent states that the Regents of the University of California have no parent companies or non-wholly owned subsidiaries.

STATEMENT OF THE CASE

Introduction. Respondent/Cross-Petitioner, Eli Lilly and Company ("Lilly") does not having standing to pursue its Cross-Petition because it is not presently aggrieved by the judgment of the Federal Circuit. Its proposed Cross-Petition raises no question relevant to the questions presented by the Petition of the Regents of the University of California ("Regents"). Instead, Lilly inappropriately seeks advice from this Court about the legal effect of the Indiana district court's unique factual findings that Lilly might find helpful in the future.

Background Facts. In 1977, scientists at the San Francisco campus of the University of California ("UC") discovered the DNA sequence of preproinsulin, the biological precursor to insulin. That discovery was the first successful cloning of an important animal hormone in a bacterium using recombinant DNA technology. The University of California received two United States patents for its insulin inventions. One of those patents, U.S. 4,652,525 (the "'525"), on an application filed in May 1977 (a patent-in-suit) was based on the discovery of the cDNA sequence for proinsulin and preproinsulin, using a rat model,[2] which is the underlying subject of Lilly's Cross-Petition.

Prior to UC's discovery, the NIH had issued a set of guidelines regarding genetic engineering experiments

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[2] UC used a rat model because the then existing National Institutes of Health ("NIH") guidelines, discussed *infra*, prohibited recombinant work with human DNA. Only after the federal government lifted its ban did UC clone and sequence the human insulin gene.

applicable to all researchers who received federal funding. The guidelines required NIH approval of plasmids used for recombinant DNA technology. Upon learning that a plasmid (pBR322) had been "approved" by NIH, UC scientists began using that plasmid in January 1977. Later on, they learned that the NIH Director had yet to "certify" that particular plasmid, although its use had theretofore been "approved." As NIH later acknowledged, the guidelines were unclear about a difference between approval and certification. However, UC's earlier use of the "approved," but "uncertified" plasmid prompted an NIH investigation which resulted in complete exoneration of the UC scientists from any wrongdoing and prompted an apology from NIH to UC for the difficulties that the misguided investigation had caused UC.

Nevertheless, Lilly resurrected the charges from which UC had been completely exonerated by NIH, arguing that the UC scientists' use of an approved but not yet certified plasmid was inequitable conduct. Lilly succeeded in persuading the district court in Indiana to make findings adverse to UC on the very points upon which UC had been found blameless by NIH,[3] even

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[3] The district court found that UC had misled the PTO by stating that the rat insulin cloning experiments were performed used plasmid pMB9 (rather than pBR322), although every witness with personal knowledge of the incident testified that the experiments were conducted using pMB9, as reported. In reaching its conclusion, the district court disregarded UC's documentary proof that the data reported in the '525 specification could not have been derived from pBR322 experiments – as Lilly alleged they were – but had to have been derived from pMB9 experiments.

though those findings were legally irrelevant to the '525 claims. (Cross-Petition, App. A [*Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 39 U.S.P.Q. 2d (BNA) 1225 (S.D. Ind. 1995)]; Cross-Respondent's App. A.)

The Federal Circuit affirmed the judgment by the Indiana district court in favor of Lilly in all respects other than the district court's conclusion that the University had engaged in inequitable conduct; the Federal Circuit concluded that the lower court had misapplied the applicable law to its factual findings. (Cert. Petition, App. A [*Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997)].)

REASONS FOR DENYING THE WRIT

Lilly does not have standing to seek *certiorari* because it has not suffered any cognizable injury from the Federal Circuit's refusal to sustain the district court's conclusion of inequitable conduct.[4] A party seeking review by this Court must have suffered an adverse judgment or be otherwise presently aggrieved by the decision of a lower court. "This Court 'reviews judgments, not statements

[4] Lilly suggests that the Federal Circuit's decision overturning the district court's inequitable conduct conclusion might defeat its obtaining attorneys' fees in the future. *See* Cross-Petition at 9. Contrary to Lilly's implication, an inequitable conduct finding is neither necessary nor sufficient for an award of attorneys' fees under 35 U.S.C. section 285. *Reactive Metals and Alloys Corp. v. ESM, Inc.*, 769 F.2d 1578, 1582 (Fed. Cir. 1985); *Orthopedic Equipment Company, Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1384 (Fed. Cir. 1983).

and opinions.'" *California v. Rooney*, 483 U.S. 307, 311 (1987) (*per curiam*) (quoting *Black v. Cutter Laboratories*, 351 U.S. 292, 297 (1956)). In *Rooney*, the Court dismissed California's writ of *certiorari* as improvidently granted. That the lower court's analysis "may have been adverse to the State's long-term interests does not allow the State to claim status as a losing party for the purposes of this Court's review." 483 U.S. at 311.

Even if it were assumed that Lilly had standing to seek review of the questions it presents, none is worthy of this Court's attention. The Cross-Petition merely states Lilly's view of the importance to it of the Indiana district court's factual findings; it also questions the application of settled law to those unique findings. Lilly's invitation to the Court to intervene in policy decisions relating to government funding of genetic engineering has heretofore been rejected. Here, as in *Diamond v. Chakrabarty*, 447 U.S. 303, 316-17 n.11 (1980), Lilly's arguments "should be addressed to the political branches of the Government, the Congress, and the Executive, and not to the courts." 447 U.S. at 317.[5]

If the Court issues a GVR order, as requested in Petitioner's Reply to Brief in Opposition, and the cause is ultimately remanded for a new trial in California, Lilly

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[5] *See also, In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995) (differentiating patent requirements from other governmental requirements about the patented product and chastising the Commission and the Board of Patent Appeals for "confus[ing] the requirements under the law for obtaining a patent with the requirements" that must be met to obtain regulatory approval to market or use the product).

can present its evidence and make its arguments to a court with proper venue.

Respectfully submitted,

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APPENDIX A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, Plaintiffs, -vs- ELI LILLY AND COMPANY, Defendant.	MDL DOCKET NO. 912 IP 92-0224-C-D/G

JUDGMENT

The Court having heretofore heard the evidence in the above entitled action, sitting without a jury, and having this day filed its findings of fact and conclusions of law in the form of a Memorandum of Opinion reading as follows: (H. I.)

NOW THEREFORE, in conformity therewith, IT IS CONSIDERED AND ADJUDGED that plaintiffs, Regents of the University of California, take nothing by their complaint.

IT IS FURTHER CONSIDERED AND ADJUDGED that the defendant, Eli Lilly and Company, does not infringe either United States Patent Number 4,652,525 (the '525 patent) or United States Patent Number 4,431,740 (the '740 patent).

IT IS FURTHER CONSIDERED AND ADJUDGED that the '525 patent's claims to the mammalian and vertebrate genera and to the human species are invalid for lack of an enabling disclosure.

IT IS FURTHER CONSIDERED, ADJUDGED AND DECREED that the '525 patent is unenforceable by reason of inequitable conduct of the patentees in that they intentionally omitted material information to the Patent Office, to-wit, the use of pBR322 in their research.

IT IS FURTHER CONSIDERED, ADJUDGED AND DECREED that the '740 patent is unenforceable by reason of inequitable conduct of the patentees in that they intentionally failed to disclose material information (the existence of EPA-1929) to the Patent Office.

IT IS FINALLY CONSIDERED AND ADJUDGED that the plaintiffs pay the costs of this action.

Dated this 11th day of December, 1995.

/s/ S. Hugh Dillin
S. Hugh Dillin, Judge